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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,308	02/20/2002	Harvey B. Buck	BMID 9916 US	1961

32842 7590 06/17/2004

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EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT PAPER NUMBER

1753

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/069,308	BUCK ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	ALEX NOGUEROLA	1753	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23-27 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 13, 16, 17, 19, 20 and 22 is/are rejected.
- 7) ☒ Claim(s) 3-12, 14, 15, 18 and 21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12032003</u>  | 6) <input type="checkbox"/> Other: ____                                     |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 13, 16, 17, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuypers (EP 0396788 A1), hereafter “Kuypers.”

Addressing claim 1, Kuypers teaches a method for monitoring analyte concentration in a biological fluid by use of a sensor (abstract), the method comprising the steps of

providing a sensor comprising a volume of hydrophilic medium (hydrogel, Figure 3) for retaining an amount of analyte proportionate to the concentration of analyte in a biological fluid in contact with the sensor, an enclosure (18) for the analyte retention volume, an electrode (W.E. (working electrode) or reference electrode) in contact with the hydrophilic medium, a redox enzyme (G.O.D. (glucose oxidase)) in contact with the medium, and an electron transfer mediator (oxygen) for facilitating transfer of electrons between the enzyme and the electrode (page 2, lines 38-48), the enzyme substantially not capable of transferring electrons to or from components of the biological fluid other than the analyte (page 2, lines 1-48),

contacting the biological fluid with the sensor (Figure 3) and at initially predetermined intervals intermittently applying a potential to the electrode sufficient to oxidize the electron

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mediator (Figure 8 and page 4, lines 3-16) and sensing current through the electrode as a function of the duration of the applied potential (Figure 8);

maintaining the applied mediator oxidizing potential at least for a period of time sufficient to determine the rate of change of current with time through the electrode (Figures 1, 7, and 8), and

correlating the current flow with the current flow for known concentration of the analyte in the retention medium (page 6, lines 46-56 and page 3, lines 18-26, which teaches that the current is proportional to the analyte concentration and using a comparison programme).

Addressing claims 2 and 17, although not stated, in the embodiment of Figure 1 the intervals (A) in Figure 1) between the intermittent applied potentials ((B) in Figure 1) are less than the time necessary for the concentration of the analyte in the retention volume to equilibrate with the that in the biological fluids in contact with the enclosure because during said intervals the applied potentials are excitation potentials, which induce electrochemical reaction (note the current rise during the intervals (A) in Figure 1 and see page 4, lines 3-16; and page 4, line 46 – page 5, line 8).

Addressing claim 13, the electron mediator is reduced and oxidase in Kuypers (page 4, lines 3-16 and page 2, lines 38-47).

Addressing claim 16, Kuypers discloses an auxiliary electrode (24) at which intermittent pulses are implicitly applied as claimed (page 6, line 57 – page 7, line 2).

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Addressing claim 22, Kuypers discloses a programmable controller as claimed (Figures 7 and 8).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuypers (EP 0396788 A1), hereafter "Kuypers."

Kuypers teaches a method for monitoring analyte concentration in a biological fluid by use of a sensor (abstract), the method comprising the steps of

providing a sensor comprising a volume of hydrophilic medium (hydrogel, Figure 3) for retaining an amount of analyte proportionate to the concentration of analyte in a biological fluid in contact with the sensor, an enclosure (18) for the analyte retention volume, an electrode (W.E. (working electrode) or reference electrode) in contact with the hydrophilic medium, a redox enzyme (G.O.D. (glucose oxidase)) in contact with the medium, and an electron transfer mediator (oxygen) for facilitating transfer of electrons between the enzyme and the electrode (page 2, lines 38-48), the enzyme substantially not capable of transferring electrons to or from components of the biological fluid other than the analyte (page 2, lines 1-48),

contacting the biological fluid with the sensor (Figure 3) and at initially predetermined intervals intermittently applying a potential to the electrode sufficient to oxidize the electron mediator (Figure 8 and page 4, lines 3-16) and sensing current through the electrode as a function of the duration of the applied potential (Figure 8);

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maintaining the applied mediator oxidizing potential at least for a period of time sufficient to determine the rate of change of current with time through the electrode (Figures 1, 7, and 8), and

correlating the current flow with the current flow for known concentration of the analyte in the retention medium (page 6, lines 46-56 and page 3, lines 18-26, which teaches that the current is proportional to the analyte concentration and using a comparison programme).

Kuypers discloses an auxiliary electrode (24) at which intermittent pulses are implicitly applied as claimed as per Applicants' claim 16 (page 6, line 57 – page 7, line 2).

Kuypers does not mention modifying the intervals or the duration of current flow based on previous measurement results; however, barring evidence to the contrary, such as unexpected results. It would have been obvious to one with ordinary skill in the art at the time of the invention to use results from previous measurements to optimize the parameters of future measurements.

*Allowable Subject Matter*

7. Claim 3-12, 14, 15, 18, and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
8. Claim 23-27 are allowed.
9. The following is a statement of reasons for the indication of allowable subject matter:
  - a) Claims 3, 4, 14, and 15: the nonobvious limitation in the combination of limitations of each of claims 3, 4, 14, and 15 is the requirement that the redox enzyme be glucose dehydrogenase. The redox enzyme in Kuypers is glucose oxidase. It would not have been obvious to substitute glucose dehydrogenase for glucose oxidase because the potential pulses in Kuypers are used to ensure adequate oxygen for the enzyme reaction. Glucose dehydrogenase is oxygen independent (see CAPLUS abstract of Tang et al., "Oxygen effects on glucose meter measurements with glucose dehydrogenase and oxidase based test strips for point-of-care testing," *Critical Care Medicine* (2001), 29(5), 1062-1070 and see col. 3, ll. 62-64 in Wong et al. (US 6,312,888 B1)), so the pulsed potentials would not be necessary;



b) Claim 5: the nonobvious limitation in the combination of limitations is the requirement that the electron mediator be osmium (bis-bipyridyl) pyridinium chloride). The electron mediator in Kuypers is oxygen;

c) Claim 6: the nonobvious limitation in the combination of limitations is the requirement that the electron mediator and redox enzyme be entrapped in a hydrophilic matrix on the electrode. In Kuypers the electron mediator (oxygen) can travel through the sensor layers (page 5, lines 35-48);

d) Claims 7 and 18: the nonobvious limitation in the combination of limitations of each of claims 7 and 18 is the requirement that the intervals are increased incrementally for a series of applied potentials. In Kuypers the intervals are constant (Figures 1, 7, and 8);

e) Claims 8 and 9 depend from allowable claim 7;

f) Claims 10 and 21: the nonobvious limitation in the combination of limitations is the requirement in each of claims 10 and 21 that the interval be substantially equal to or greater than the time required for the analyte concentration in the retention volume to equilibrate with that in the biological fluid. In Kuypers, as seen in Figures 1 and 8 the current changes during the intervals implying non-equilibration;

g) Claims 11 and 12 depend from allowable claim 10;

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h) Claim 23: the nonobvious limitation in the combination of limitations is the requirement of a hydrophilic matrix comprising poly(pyrrole-3-acetic acid), and electron mediator and a redox enzyme. The hydrophilic matrix in Kuypers is not specified. Adeloju et al. ("Pulsed-amperometric detection of urea in blood samples on a conducting polypyrrole-urease biosensor," *Analytica Chimica Acta* 341 (1997) 155-160) uses polypyrrole not poly(pyrrole-3-acetic acid) (2.2 *Electropolymerisation of polypyrrole-urase film* on page 156); and

i) Claims 24-27 depend directly or indirectly from allowable claim 23.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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June 14, 2004